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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,623 | 12/01/2000 | Chang Yi Wang | 1151-4153US1 | 8939 |

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| EXAMINER | |
|---|---|
| JAMROZ, MARGARET E | |
| ART UNIT | PAPER NUMBER |
| 1644 | 13 |

DATE MAILED: 03/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Offic Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/701,623 | WANG ET AL. | |
| | Examiner | Art Unit | |
| | Margaret E Jamroz | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *restriction election facsimile* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

***Restriction Requirement***

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

In view of the delays in the mail at the present time, the office strongly encourages faxing responses.

***Restriction***

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

1. Claims 1-2 and 19-20, drawn to SEQ ID NO: 5, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, immunologically functional analogs thereof.

2. Claims 1-2 and 19-20, drawn to SEQ ID NO: 6, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

3. Claims 1-2 and 19-20, drawn to SEQ ID NO: 7, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

4. Claims 1-2 and 19-20, drawn to SEQ ID NO: 8, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

5. Claims 1-2 and 19-20, drawn to SEQ ID NO: 84, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

6. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 5.

7. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 6.

8. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 7.

9. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 8.

10. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 84.

11. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 14, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

12. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 15, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

13. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 17, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

14. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 18, or a branched polymer, a cross-lined polymer, and a pharmaceutical composition thereof.

15. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 19, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

16. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 20, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

17. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 21, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

18. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 22, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

19. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 23, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

20. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 24, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

21. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 25, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

22. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 26, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

23. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 27, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

24. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 85, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

25. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 87, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

26. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 88, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

27. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 90, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

28. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 91, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

29. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 5, a branched polymer thereof, or a cross-lined polymer thereof.

30. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 6, a branched polymer thereof, or a cross-lined polymer thereof.

31. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 7, a branched polymer thereof, or a cross-lined polymer thereof.

32. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 8, a branched polymer thereof, or a cross-lined polymer thereof.

33. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 84, a branched polymer thereof, or a cross-lined polymer thereof.

34. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 14, a branched polymer thereof, or a cross-lined polymer thereof.

35. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 15, a branched polymer thereof, or a cross-lined polymer thereof.

36. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 17, a branched polymer thereof, or a cross-lined polymer thereof.

37. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 18, a branched polymer thereof, or a cross-lined polymer thereof.

38. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 19, a branched polymer thereof, or a cross-lined polymer thereof.

39. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 20, a branched polymer thereof, or a cross-lined polymer thereof.

40. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 21, a branched polymer thereof, or a cross-lined polymer thereof.

41. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 22, a branched polymer thereof, or a cross-lined polymer thereof.

42. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 23, a branched polymer thereof, or a cross-lined polymer thereof.

43. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 24, a branched polymer thereof, or a cross-lined polymer thereof.

44. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 25, a branched polymer thereof, or a cross-lined polymer thereof.

45. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 26, a branched polymer thereof, or a cross-lined polymer thereof.

46. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 27, a branched polymer thereof, or a cross-lined polymer thereof.

47. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 85, a branched polymer thereof, or a cross-lined polymer thereof.

48. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 87, a branched polymer thereof, or a cross-lined polymer thereof.

49. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 88, a branched polymer thereof, or a cross-lined polymer thereof.

50. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 89, a branched polymer thereof, or a cross-lined polymer thereof.

51. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 5.

52. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 6.

53. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 7.

54. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 8.

55. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 84.

56. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 5.

57. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 6.

58. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 7.

59. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 8.

60. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 84.

4. The inventions listed as Groups 1-60 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 CFR 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, (SEQ ID NO: 5, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, immunologically functional analogs thereof). Further pursuant to 37 CFR 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

***Species Election***

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(1) If applicant elects one of Groups 6-10, applicant is further required to elect a specific peptide conjugate wherein A is a specific amino acid (e.g. proline) or a specific general immunostimulatory sequence and wherein n is a specific number (e.g. 0); wherein B is chosen from the specific amino acids (such as one of those recited in claim 6) and wherein 0 is a specific number (e.g. 1); wherein the IgE-CH3 domain antigen is a specific sequence (e.g. SEQ ID NO: 5); wherein Tm is a specific sequence of amino acids constituting a helper T cell epitope (e.g. SEQ ID NO: 9) and wherein m is a specific number (e.g. 1); and wherein X is a specific amino acid; or a specific nucleic acid sequence which encode them, respectively.

The claims are deemed to correspond to the species listed above: claims 4, 5, and 6.

(2) If applicant elects one of Groups 11-28, applicant is further required to elect a specific branched polymer comprising a specific lysine core (e.g. lysine) covalently attached to a specific number of peptide conjugates.

The claims are deemed to correspond to the species listed above: claims 4, 5, 6, and 22.

(3) If applicant elects one of Groups 29-50, applicant, applicant is further required to elect a specific method for inducing anti-IgE production comprising administering a specific peptide conjugate wherein A is a specific amino acid (e.g. proline) or a specific general immunostimulatory sequence and wherein n is a specific number (e.g. 0); wherein B is chosen from the specific amino acids (such as one of those recited in claim 6) and wherein 0 is a specific number (e.g. 1); wherein the IgE-CH3 domain antigen is a specific sequence (e.g. SEQ ID NO: 5); wherein Tm is a specific sequence of amino acids constituting a helper T cell epitope (e.g. SEQ ID NO: 9) and wherein m is a specific number (e.g. 1); and wherein X is a specific amino acid; or administering a specific branched polymer comprising a specific lysine core (e.g. lysine) covalently attached to a specific number of peptide conjugates (e.g. two).

The claims are deemed to correspond to the species listed above: claims 4, 5, 6, and 26.

(4) If applicant elects one of Groups 56-60, applicant is required to elect a specific nucleic acid comprising a sequence which encodes a specific peptide conjugate wherein A is a specific amino acid (e.g. proline) or a specific general immunostimulatory sequence and wherein n is a specific number (e.g. 0); wherein B is chosen from the specific amino acids (such as one of those recited in claim 6) and wherein 0 is a specific number (e.g. 1); wherein the IgE-CH3 domain antigen is a specific sequence (e.g. SEQ ID NO: 5); wherein Tm is a specific sequence of amino acids constituting a helper T cell epitope (e.g. SEQ ID NO: 9) and wherein m is a specific number (e.g. 1); and wherein X is a specific amino acid; or administering a specific branched polymer comprising a specific lysine core (e.g. lysine) covalently attached to a specific number of peptide conjugates (e.g. two).

The claims are deemed to correspond to the species listed above: claims 1, 4, 5, 6, and 28.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
March 19, 2002

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640